DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ray Co., Ltd.
% Mr. Andrew Paeng, Consultant
4747 Hoen Ave
Santa Rosa, CA 95405

April 17, 2015

Re: K142247
Trade/Device Name: RAYSCAN α-Expert 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: March 20, 2015
Received: March 23, 2015

Dear Mr. Paeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142247

Device Name

RAYSCAN α–Expert3D

Indications for Use *(Describe)*

RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBCT technique, to generate dentomaxillofacial 3D images.
The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.
2D Image is obtained using the standard narrow beam technique.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) Summary

510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date:

APPLICANT RAY Co.,Ltd

ADDRESS #332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 443-823, Korea

Manufacturer RAY Co.,Ltd
332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 443-823, Korea

TEL : +82-31-605-1000
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Contact Person Kyungha Seo
e-mail : Kyungha.seo@raymedical.co.kr

Device Name

Trade/Proprietary Name: RAYSCAN α–Expert 3D
Common Name: Dental panoramic/tomography and cephalometric x-ray system

Classification

Classification Name: Computed tomography x-ray system (21 CFR 892.1750)
Class : II
Product code : OAS
Panel : Radiology

Predicate device

Parameter	Predicated Device-1	Predicated Device-2
Device Name	RAYSCAN α–Expert3D	RAYSCAN α–Expert3D
Manufacturer	RAY Co., Ltd	RAY Co., Ltd
510(K) Number	K122981 Traditional 510k	K131695 Special 510k
Classification name	Computed tomography x-ray system	Computed tomography x-ray system
Regulation number	892.1750	892.1750
Primary product code	OAS	OAS

Description

System purpose RAYSCAN α-3D, SM3D, M3DS and M3DL are 3D computed tomography for scanning hard tissues like bone and teeth.
By rotating the c-arm which is embedded with high voltage generator all-in-one x-ray tube and a detector on each end, fault surface image of whole body is attained by recombining data from the same level that are scanned from different angle. Panoramic image scanning function for attaining image of whole teeth, and cephalometric scanning option for attaining cephalic image are included.

Detector Options:

Specific models according to the detector type; CT, Pano and Ceph mounted in the RAYSCAN α- Expert 3D system are classified as shown below.

RAYSCAN α-3D: CT(model-C10900D)+PANO(model-C10500D)
RAYSCAN α-SM3D: CT(model-C10900D)+PANO(model-C10500D)+
Scan Ceph(model-XID-C24DS)
RAYSCAN α-M3DL: CT(model-C10900D)+PANO(model-C10500D)+
One shot ceph(model-PaxScan 4336X)
RAYSCAN α-M3DS: CT(model-C10900D)+PANO(model-C10500D) +
One shot ceph(model-PaxScan 2530C)

Non-clinical & clinical consideration report for all types of Detectors included in the RAYSCAN α- Expert3D system are prepared in compliance with 21CFR807.92(a)(7) of the FDA.

The Detector model mounted in our Dental X-ray system RAYSCAN α-M3DL [One shot Ceph] is the PaxSca 4336X model. The Non-clinical report provided by Varian, manufacturer of the Detector, was submitted in place of the Non-clinical report regarding the Solid state Detectors required by FDA.
The Non-clinical report provided by the manufacturer Varian includes and describes the Non-Clinical Data for both models PaxScan 4336W and PaxScan 4336WX. In particular the PaxScan 4336W model includes a wireless detector function however PaxScan 4336X, the detector mounted in our RAYSCAN α-M3DL [One shot Ceph] system is a detector without the wireless function, therefore the data for wireless function is not attached.

SMARTDent software for processing and archiving is optional.

Indication for use

RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images.
The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.
2D Image is obtained using the standard narrow beam technique.

"CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

Patient population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.
There is no restriction for ethnic group, Gender, weight, health, or condition.
We recommend patients for x-ray diagnostic radiation exposure to be over 5 years old.

Device functions

The purpose of this unit is diagnose clinical structures of a tooth and head areas mainly by using the characteristics of permeability from X-ray. The principle of functioning and formations are as following. The machine is made of X-ray generator and arms in which transfers X-ray signals to a sensor in 2D. Also, an object that has a magnification is required in a distance. Moreover, the unit has to be adjustable depending on height of a patient and PC system to reconstruct an image.

The arm parts are controlled for rotating and linear moving to synchronize between the sensor and X-ray generator to get the image of interests. The purpose of this mechanism is to provide the images in 2D or/and 3D as preferred to diagnose in a monitor. CBCT provides in 3D images as reconstructed and Panorama is to diagnose the structures in a panoramic view. Cephalometric allows for orthodontic treatment. These 3 functions could be in 1 system, Panorama with Cephalometric, or Panorama only system depending on the needs. To provide the features as mentioned above, digital transferring from permeated X-ray to absorbing to the sensor is essential and all the process are proceed in Detector. Detector transfers X-ray to light depending on the structure materials. Detector is separated into indirect method that the light is changed to digital signals on photodiode and direct method in which the light is directly transferred to digital signal. This unit is using both direct and indirect method depending on the interior structure materials.

Operating principle of the detector

X-ray data entered into the detector from an outside source is converted to visible ray by detector's Scintillator and The visible ray is transferred to CMOS ASIC and converted to an Electric signal to form an image signal.

Then the signal is changed to a Digital form and through the high speed LAN cable, the acquired image data is transmitted to the PC.

Acquired resulting image is displayed on the monitor by the PC Software.

Comparison of the detector

One shot ceph detector installed on the One shot ceph option RAYSCAN α-Multi3D in Predicate devices RAYSCAN α–Expert 3D[K122981, Traditional] and RAYSCAN α-

Expert3D[K131695, special] is SDX-4336CP (model name).
Whereas the One shot Ceph type mounted in the proposed RAYSCAN α–Expert 3D[K142247, Traditional] offers 2 models depending on the detector size.
In RAYSCAN α-M3DL, PaxScan 4336X(size: 42.4cm*35.3cm) detector is mounted and in RAYSCAN α-M3DS, PaxScan 2530C(24.9cm*30.2cm) detector is installed.
Meaning if One shot Ceph option is limited to RAYSCAN α-Multi3D in the predicate devices RAYSCAN α–Expert 3D[K122981, Traditional] and RAYSCAN α-Expert3D[K131695, special] then
The One shot Ceph option for the proposed device RAYSCAN α–Expert 3D[K142247, Traditional] offers 2 models RAYSCAN α-M3DL and RAYSCAN α-M3DS according to the detector size.

The detector installed in the Predicate device RAYSCAN α-Multi3D and Proposed devices RAYSCAN α-M3DL and RAYSCAN α-M3DS presents no differences in the technical principle and characteristics and only the manufacturer of the detector and part of the specification were changed.
Differences in the detector SDX-4336CP installed in RAYSCAN α-Multi3D of the Predicate device and detectors PaxScan 4336X and PaxScan 2530C mounted in the Proposed device models RAYSCAN α-M3DL and RAYSCAN α-M3DS are shown in the following table.
The detector for 2 newly added models RAYSCAN α-M3DL(PaxScan 4336X) and RAYSCAN α-M3DS(PaxScan 2530C) share the same manufacturer as well as the same technical characteristics, only difference in the detector is its size. Detector in the RAYSCAN α-M3DL(PaxScan 4336X) has the size 42.4 (V)cm x 35.3 (H) cm and size of the detector in RAYSCAN α-M3DS is 24.9(V)cm x 30.2(H)cm.

In addition, among the detector option of the RAYSCAN α-Expert3D included in RAYSCAN α–Expert 3D[K122981, Traditional] and RAYSCAN α-Expert3D[K131695, special] of the Predicate device, basic(RAYSCAN α-3D) and scan type(RAYSCAN α-SM3D) are completely identical.

<table>
<tr><td colspan="2" rowspan="4">Division</td><td>Proposed Device</td><td>Predicate Device #1</td><td>Predicate Device #2</td></tr>
<tr><td>RAYSCAN α–Expert3D</td><td>RAYSCAN α–Expert3D</td><td>RAYSCAN α–Expert3D</td></tr>
<tr><td>K142247</td><td>K122981</td><td>K131695</td></tr>
<tr><td>RAY Co., Ltd.</td><td>RAY Co., Ltd.</td><td>RAY Co., Ltd.</td></tr>
<tr><td rowspan="2">CT detector</td><td>Manufacturer</td><td rowspan="2">Same as predicate device #1</td><td>Hamamatsu</td><td rowspan="2">Same as predicate device #1</td></tr>
<tr><td>Model</td><td>C10900D</td></tr>
<tr><td colspan="2">Traditional</td><td>Traditional</td><td>Special</td></tr>
</table>

	Scintillator Material		CsI (Indirect type)	
	Total pixel area		124.8(W)x124.8(H)mm	
	Total pixel		624x624	
	Pixel size		200um	
	Limiting resolution		2.5lp/mm	
	Power supply/Main		5VDC / 1250mA	
	MTF		60% at 1 LP/mm	
	DQE		0.23 at 1 LP/mm	
	VOXEL (at Jaw protocol)		280μm	
PANO detector	Manufacturer	Same as predicate device #1	Hamamatsu	Same as predicate device #1
	Model		C10500D	
	Scintillator Material		CsI (Indirect type)	
	Total pixel area		6.0(W)x1512(H)mm	
	Total pixel		60x1512	
	Pixel size		100um	
	Limiting resolution		5.0lp/mm	
	Power supply/Main		5VDC / 1100mA	
	MTF		70% at 1LP/mm	
	DQE		0.5 at 1LP/mm	
Ceph (Scan) detector	Manufacturer	Same as predicate device #2	N/A (No attached Scan Ceph)	i3System
	Model			XID-C24DS
	Scintillator Material			CdTe (Direct type)
	Total pixel area			4.8(W)x240(H)mm
	Total pixel			48x2400
	Pixel size			100um
	Limiting resolution			5.0lp/mm
	Power supply/Main			5VDC / 2A
	MTF			75% at 1LP/mm

	DQE			0.88 at 1LP/mm
Ceph (One shot, Large Size) detector	Manufacturer	Varian	Same as predicate device #1	Samsung Mobile Display
	Model	PaxScan 4336X		SDX-4336CP
	Scintillator Material	GADOX (Indirect type)		CsI (Indirect type)
	Total pixel area	427(W)x356(H)mm		43.2 x 36.0 cm
	Total pixel	3072x2560		2880 x 2400
	Pixel size	139um		150 um
	Limiting resolution	3.6lp/mm		3.3 lp/mm
	Power supply/Main	100-240VAC, 47-63Hz		100-240VAC, 50/60Hz
	MTF	54% at 1LP/mm		45% at 1LP/mm
	DQE	0.2 at 1LP/mm		0.41 at 1P/mm
Ceph (One shot, Standard Size) detector	Manufacturer	Varian	N/A (No attached one shot CEPH.)	N/A (No attached one shot CEPH.)
	Model	PaxScan 2530C		
	Scintillator Material	GADOX (Indirect type)		
	Total pixel area	302(W)x249(H)mm		
	Total pixel	2176x1792		
	Pixel size	139um		
	Limiting resolution	3.6lp/mm		
	Power supply/Main	100-240VAC, 47-63Hz		
	MTF	54% at 1LP/mm		
	DQE	0.2 at 1LP/mm		

Information for detector own 510(K) number or system in which it was cleared 510(k) number.

Division	Model	Manufacturer	Own 510(K) number	System in which it was cleared 510(k) number.

CT	C10900D	Hamamatsu	No	1) System name: RAYSCAN α–Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K122981
Pano	C10500D	Hamamatsu	No	1) System name: RAYSCAN α–Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K122981
Scan Ceph	XID-C24DS	i3System	No	1) System name: RAYSCAN α–Expert3D 2) Manufacturer: RAY CO., LTD 3) 510(K) Number: K131695
One shot Ceph	PaxScan 4336X	Varian	No	1) System name: Multix Fusion 2) Manufacturer: Siemens 3) 510(K) Number: K121513
One shot Ceph	PaxScan 2530C	Varian	No	1) System name: Unknown 2) Manufacturer: Unknown 3) 510(K) Number: Unknown

Statement of Substantial Equivalence

Parameter	Proposed Device	Predicated Device	Predicated Device
Manufacturer	RAY Co., Ltd.	RAY Co., Ltd.	RAY Co., Ltd.
Device name	RAYSCAN α–Expert3D	RAYSCAN α–Expert3D	RAYSCANα–Expert3D
510(K) Number	K142247 Traditional 510k	K122981 Traditional 510k	K131695 Special 510k
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
Indications for use	RAYSCAN α–Expert 3D panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique.	RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalo Traditional 510k stat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.2D Images are obtained using the standard narrow beam technique.	RAYSCAN α–Expert 3D panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique..

Mode of Operation	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading
3D technology	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography
Performance Specification	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot type	1) CBCT Computed tomography 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type
Functional Option	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-SM3D: CT + PANO + SCAN CEPH RAYSCAN α-M3DS: CT + PANO + One shot(9.8 X 11.9 inch) RAYSCAN α-M3DL: CT + PANO + One shot(16.8 X 14.0 inch)	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-Multi 3D: CT + PANO + One shot	Base RAYSCAN α-3D : CT+PANO Option(CEPH) RAYSCAN α-SM3D: CT + PANO + SCAN RAYSCAN α-Multi 3D: CT + PANO + One shot

Exam mode	CT	Standard Implant Surgical guide Endo Sinus TMJ	Standard Implant Surgical guide Endo Sinus TMJ	Standard Implant Surgical guide Endo Sinus TMJ
	PANO	Standard(Normal) TMJ Sinus Segmentation (Individual Tooth) Bitewing Orthogonal	Normal(Adult) Pedodontics(Children) TMJ Sinus	Standard(Normal) TMJ Sinus Segmentation (Individual Tooth) Bitewing Orthogonal
	Ceph (Optional)	Posterior/Anterior Lateral SMV Carpus Reverse Town's Waters Lateral wide	PA,AP Lateral SMV Carpus Reverse Town's Waters	Posterior/Anterior Lateral SMV Carpus Reverse Town's Waters Lateral wide
Detector Type		1) Computed Tomography(CT) : Flat panel X-ray sensor 2) Pano: Flat panel X-ray sensor 3) Ceph(Option): - Scan type: CdTe Direct flat panel sensor - One shot type: Amorphous Silicon	1) Computed Tomography(CT) : Flat panel X-ray sensor 2) Pano: Flat panel X-ray sensor 3) Ceph(Option): - One shot type: Flat panel X-ray sensor	1) Computed Tomography(CT) : Flat panel X-ray sensor 2) Pano: Flat panel X-ray sensor 3) Ceph(Option): - Scan type: CdTe Direct flat panel sensor - One shot type: Flat panel X-ray sensor

Exposure switch Type	"Deadman" Button type	Deadman" Button type	"Deadman" Button type
Main Components	Ceph Apparatus	Ceph Apparatus	Ceph Apparatus
	Vertical Carriage	Vertical Carriage	Vertical Carriage
	Rotator	Rotator	Rotator
	X-RAY Generator	X-RAY Generator	X-RAY Generator
	X-ray tube	X-ray tube	X-ray tube
	High Frequency Generator	High Frequency Generator	High Frequency Generator
	Column	Column	Column
	Touch monitor (panel)	Touch monitor (panel)	Touch monitor (panel)
	Detector - CT - Panoramic - Scan type Cephalometric - One shot type Cephalometric: 24.9(V) x 30.2(H) cm - One shot type Cephalometric: 42.4 (V) x 35.3 (H) cm	Detector - CT - Panoramic - One shot type Cephalometric	Detector - CT - Panoramic - Scan type Cephalometric - One shot type Cephalometric
	Chinrest	Chinrest	Chinrest

	Head rest	Head rest	Head rest
	Automatic Collimator	Automatic Collimator	Automatic Collimator
	Exposure switch	Exposure switch	Exposure switch
	Emergency stop switch	Emergency stop switch	Emergency stop switch
	Console PC set	Console PC set	Console PC set
Automatic Collimator	CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams
Display Type	TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel
Class	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1
Focal size	0.5	0.5	0.5
Field of View(CT)	90x90mm	90x90mm	90x90mm
X-ray Voltage	60~90kVp	60~90kVp	60~90kVp
X-ray Current	4~17mA	4~17mA	4~17mA

Total Filtration	2.6 ㎜ Al equivalent	2.6 ㎜ Al equivalent	2.6 ㎜ Al equivalent
Detector Pixel size	Computed Tomography(CT): 200 ㎛	Computed Tomography(CT): 100 ㎛	Computed Tomography(CT): 100 ㎛
	Pano: 100 ㎛	Pano: 100 ㎛	Pano: 100 ㎛
	Ceph[Scan type]: 100 ㎛		Ceph[Scan type]: 100 ㎛
	Ceph[One shot type, installed in α-M3DS]: 139 ㎛	Ceph[One shot type]: 150 ㎛	Ceph[One shot type]: 150 ㎛
	Ceph[One shot type, installed in α-M3DL]: 139 ㎛		
Magnification	CT : 1.39	CT : 1.39	CT : 1.39
	Pano : 1.31	Pano : 1.31	Pano : 1.31
	Ceph[Scan type] : 1.11		Ceph[Scan type] : 1.11
	Ceph[One shot type, α-M3DS] : 1.12	Ceph[One shot type, α-Multi3D]: : 1.13	Ceph[One shot type, α-Multi3D]: : 1.13
	Ceph[One shot type, α-M3DL] : 1.13		
Scan time	CT : below 14sec	CT : below 14sec	CT : below 14sec
	Pano : below 14sec	Pano : below 14sec	Pano : below 14sec
	Ceph[Scan type] : below 18sec		Ceph[Scan type] : below 18sec

	Ceph[One shot type, α-M3DS]: below 2sec	Ceph[One shot type, α-Multi3D]: 0.3sec~3.0sec	Ceph[One shot type, α-Multi3D]: 0.3sec~3.0sec
	Ceph[One shot type, α-M3DL]: below 2sec		
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Image acquisition	Giga-Ethernet Network	Giga-Ethernet Network	Giga-Ethernet Network
Total Height	Max 2,296mm	Max 2,296mm	Max 2,296mm
Weight	1) Computed Tomography(CT) + Panoramic(PANO)=148kg(326lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (Scan type)= 164kg (362lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (One shot type, installed in α-M3DS)= 166kg (366lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (One shot type, installed in α-M3DL)= 166kg (366lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO)=148kg(326lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (One shot type)=165kg(364lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO)=148kg(326lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (Scan type)=164kg (362lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Cephalostic (One shot type)=165kg(364lb) ± 10%
Type of installation	Wall or floor mount	Wall or floor mount	Wall or floor mount

Patient position	Standing / Wheelchair	Standing / Wheelchair	Standing / Wheelchair
Applicable Standards	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-63 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-44 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-44 IEC 60601-1-2
Certificate Product	CE0120(MDD93/42/EEC)	CE0120(MDD93/42/EEC)	CE0120(MDD93/42/EEC)

Safety and Effectiveness Information

Electrical, mechanical and environmental safety testing according to standard of IEC 60601-1: 2005 + CORR.1(2006) + CORR.2(2007), IEC 60601-1-3: 2008(Second Edition), IEC 60601-2-28: 2010(Second Edition) and IEC 60601-2-63: 2012(first Edition) were performed.
EMC testing was conducted in accordance with the standard IEC 60601-1-2: 2007(Edition 3.0).

The software of RAYSCAN α–Expert3D has been validated according to FDA "Guidance for the Content d Premarket Submissions for Software Contained in Medical Devices" and applicable requirements contained in the guidance document.

Bench testing was conducted according to FDA Guidance "Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench"
Bench testing is used to assess whether or not the parameter measured required for describing functionalities related to imaging properties of the dental X-ray device and patient dosage satisfies the designated tolerance.
Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4 and IEC 61223-3-5.
All test results were satisfactory.

Non-clinical and test was conducted for imaging performance of the proposed detector in accordance with FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices".
All test results were satisfactory.
Both of the predicate device and proposed device are based on Csi scintillator designed for general radiography. MTF (Modulation Transfer Function) and DQE (Detective Quantum Efficiency) were test and measured by IEC 62220-1.
RAYSCAN α-M3DL and RAYSCAN α-M3DS system's new sensor and compared with the predicate device with regard to Modulation Transfer Function (MTF) and Device Quantum Efficiency (DQE). Base on the Non-clinical test result, even though the new Csi detector differs in term of the pixel size and active area, the diagnostic image quality of the new detector is equal or better than those of the predicate device and there is no significant difference in efficiency and safety.

Clinical considerations were conducted according to FDA Guidance "Format for Traditional and Abbreviated 510(k)s, section 20".
Clinical images were provided these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in

addition to the laboratory performance data to show that the complete system works as intended.
For clinical testing, two licensed practitioners/clinicians observed and verified that dental X ray system from RAYSCAN α.
The clinical imaging samples are collected from the new 2 one shot detector on propose device at the 2 offices where the predicate device is installed on clinical consideration report for the clinical test images. These images were gathered from the new 2 one shot ceph detector installed with RAYSCAN α-M3DL and M3DS on any protocols with random patient age, gender, and size. As licensed practitioners or clinician diagnoses of the images, it might be proved that the clinical diagnosis and structures are acceptable in the region of interests.

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.

Conclusions

Based on a comparison of intended use, indications, constructions, construction materials, principal of Operation, features and technical data, the RAYSCAN α–Expert 3D system are safe and effective to perform its intended use as well as substantially equivalent to the predicate device.